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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,538

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Klaus Abraham-Fuchs

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EXAMINER

WINSTON III, EDWARD B

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,538	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner EDWARD WINSTON	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>August 16, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on August 16, 2006.
2. Claim(s) 1-20 are currently pending and have been examined.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claimed process is eligible for patent protection under 35 U.S.C. § 101 if:

"(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines. '); Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing' '); Cochrane v. Deener, 94 U.S. 780, 788 (1876) ('A process is...an

act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').⁷ A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article.” (*In re Bilski*, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008))

Also noted in *Bilski* is the statement, “Process claim that recites fundamental principle, and that otherwise fails ‘machine-or-transformation’ test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or transformation constitutes mere ‘insignificant post-solution activity.’” (*In re Bilski*, 88 USPQ2d 1385, 1385 (Fed. Cir. 2008)). Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test.

It is also noted that the mere recitation of a machine in the preamble in a manner such that the machine fails to patentably limit the scope of the claim does not make the claim statutory under 35 U.S.C. § 101, as seen in the Board of Patent Appeals Informative Opinion *Ex parte Langemyr et al.* (Appeal 2008-1495).

Claims 1-20, as recited, is directed toward a method for (determining a degree of compliance with a performance specification assigned to a medical working practice) comprising the steps of (recording, storing, carrying out, reading, evaluating, determining). Please note that “computerized” in the preamble does not qualify as sufficient structure when (1) a computer, (2) computer-program product having instructions tangibly embodied thereon, when executed by a processor resulting in the recited steps, (3) network, etc. for example, are never recited in the body of the claim. To qualify as a statutory process, the claim should positively recite the other statutory class to which it is tied, for example by identifying the apparatus, i.e. computer, network, computer-readable medium, etc., that accomplishes the method steps or positively reciting the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. As currently written the steps recited in claims 1-20 may be performed by hand or mentally and are therefore not sufficiently tied to another statutory class. It is noted that computer is used to display however there is no indication that any of the other steps are performed by a computer and/or data received via a network, etc.

Claims 1-20 are not tied to a particular machine or apparatus nor do they transform a particular article into a different state or thing, thereby failing the machine-or-transformation test; therefore, claim 1-20 are non-statutory under § 101. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabol et al. (US 2004/0122719).

CLAIM 1.

A method for determining a degree of compliance with a performance specification assigned to a medical working practice, the method comprising:

- recording and storing data correlated with the medical working practice in a data-processing device; (see at least Paragraph 0008)
- storing test criteria for the data, correlated with the performance specification, in a test system; carrying out the working practice; reading, via the test system, the data out from the data-processing device; and evaluating, via the test system, the data with the aid of the test criteria and determining a degree of compliance with the performance specification. As stated in Paragraph [0019] of Applicants Summary, the degree of compliance may moreover lead to a simple Yes/No decision, i.e. compliance or noncompliance with the performance specification. (see at least Paragraph 0332 wherein, provided are structured video and/or audio recordings of questions and answers; Figures 1-31 Paragraph 0004 and 0008)

CLAIM 2.

The method as claimed in claim 1, wherein:

- clinical data are collected as the medical working practice, the collection process being assigned a collection protocol (Acquisition techniques) as the performance specification (see at least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 3.

The method as claimed in claim 2, wherein:

- a measurement value for a clinical study is collected from a patient as the medical working practice, and the test system sends the measurement value as a valid measurement value to a study database if the collection protocol is complied with (see at least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 4.

The method as claimed in claim 1, wherein:

- a knowledge-based system is used as the test system, and the performance specification is stored in the form of a rule set in the knowledge-based system (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 5.

The method as claimed in claim 4, wherein:

- the performance specification is stored as a module in the rule set (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 6.

The method as claimed in claim 1, wherein:

- the method is carried out automatically after each medical working practice (see at least Paragraph 0288)

CLAIM 7.

The method as claimed in claim 1, wherein:

- if the performance specification is not complied with, a decision is made as to whether it is possible to repeat the working practice and, if so, repetition is requested; and if repetition is possible, a corresponding repetition request is made to those carrying it out (see at least Paragraph 0294).

Sabol et al. does not expressly teach the specific data recited in claims 7. These differences are only found in the non-functional descriptive material and are not functionally involved in the manipulative steps of the invention nor do they alter the recited structural elements; therefore,

such differences do not effectively serve to patentably distinguish the claimed invention over the prior art. The manipulative steps of the invention would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data.

Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability as the claimed invention fails to present a new and unobvious functional relationship between the descriptive material and the substrate, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994)); *In re Ngai*, 367 F.3d 1336, 1336, 70 USPQ2d 1862, 1863-64 (Fed. Cir. 2004); *MPEP* § 2106.

CLAIM 10.

The method as claimed in claim 8, wherein:

- the performance specification is stored as a module in the rule set.

(see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under **35 USC § 101**. Refer to MPEP.

CLAIM 11.

The method as claimed in claim 9, wherein:

- the performance specification is stored as a module in the rule set.
(see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under *35 USC § 101*. Refer to MPEP.

CLAIMS 12-15.

The method as claimed in claims (2-5) wherein:

- the method is carried out automatically after each medical working practice.

CLAIMS 16 – 20.

Claim 16-20 is directed to a method for determining a degree of compliance with a performance specification assigned to a medical working practice. Claim 16-20 recites the same or similar limitations as those addressed above for Claim 7. Claim 16-20 is therefore rejected for the same reasons as set forth above for Claim 7 respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sabol et al. (US 2004/0122719) in view of Miller et al. (US 5,446,653).

CLAIMS 8 & 9.

Sabol et al. further teach(s) a method as claimed in claim 2 & 3, wherein:

- a knowledge-based system is used as the test system (see at least Figure 10-14[136])

Sabol et al. does not explicitly teach a method as in claims 2 & 3 wherein the performance specification is stored in the form of a rule set in the knowledge-based system. It would have

been obvious to one of ordinary skill in the art at the time of the invention to expand the method of Sabol et al. to include documents that are automatically generated by assembling a plurality of clauses selected from a library of clauses stored in a computer system. A rule set is assigned to each of the clauses. Each rule set provides at least one rule that must be satisfied in order to include the clause associated therewith in a document (see at least Abstract) as taught by Miller et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the process of Sabol et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON whose telephone number is (571) 270-7780. The examiner can normally be reached on MONDAY-THURDAY; 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Conner can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/E. W./
Examiner, Art Unit 3686
December 9, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686